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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/585,820

06/01/00

MERCOLONO

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CDS-221

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HM22/1023

EXAMINER

GRUN, J

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

10/23/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.
09/585,820

Applicant(s)

MERCOLINO et al.

Examiner
James L. Grun, Ph.D.

Art Unit
1641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6 Aug 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 20, 22, 23, and 25-28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 20, 22, 23, and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 06 August 2001 is acknowledged and has been entered. Claims 25-28 are newly added. Claims 1-15, 17-19, 21, and 24 have been cancelled as indicated in applicant's remarks and "Exhibit A." Claims 16, 20, 22, 23, and 25-28 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's indication that the requirement for submission of formal drawings is being held in abeyance pending the indication of allowable subject matter is acknowledged.

The specification is objected to and claims 16, 20, 22, 23, and 25-28 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that the specification contains subject matter which was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth, applicant desires simultaneous determination of forward and reverse ABO blood group yet provides no guidance for how one accomplishes such simultaneous determination with the separate combinations of anti-A antibodies and anti-B antibodies (forward), or of A-bearing cells and B-bearing cells (reverse).

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Applicant's arguments filed 06 August 2001 have been fully considered but they are not deemed to be persuasive. Applicant urges that the disclosure of Example 2 Part C provides sufficient guidance. This is not found persuasive because the example is drawn only to reverse ABO blood grouping, not simultaneous determination of forward and reverse ABO blood group.

Claims 16, 20, 22, 23, and 25-28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 16, 20, 22, 23, and 25-28, the interrelationships of the sample or samples are not clear.

In claims 23 and 28, it is not clear how the computerized imaging system is related to or further limits "visual analysis" or if the imaging system is intended to limit "spectrophotometric analysis".

Applicant's arguments filed 06 August 2001 have been fully considered but they are not deemed to be persuasive. Applicant's response has not addressed the lack of clarity as to interrelationships of one or more sample(s) in the different steps. Applicant urges that analysis of agglutination in a column agglutination cassette can be made "visually" by a technician or by computerized imaging. This is not found persuasive as these would appear as alternative analysis means, i.e. visual vs. computer imaging (see e.g. specification page 5, lines 24-25), and not as alternative "visual" analysis means as asserted.

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Claims 16, 20, 22, 23, and 25-28 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ullman (U.S. Pat. No. 4,584,277) for reasons of record in the prior rejection of the similar subject matter of claims 1-11 and 14-20. The examiner would note that recitation of column agglutination technology for visual analysis is in the alternative.

Claims 16, 20, 22, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Yves [Lapierre] et al (U.S. Pat. No. 5,338,689) for reasons of record in the prior rejection of the similar subject matter of claims 16, 17, and 19-21.

Claims 16, 20, 22, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Chachowski et al (U.S. Pat. No. 5,552,064) for reasons of record in the prior rejection of the similar subject matter of claims 16, 17, and 19-22.

Claims 16, 20, 22, 23, and 25-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ullman (U.S. Pat. No. 4,584,277) in view of Vorpahl et al (U.S. Pat. No. 5,071,774) and Chang et al (U.S. Pat. No. 4,748,129) for reasons of record in the prior rejection of the similar subject matter of claims 1-12 and 14-20. The examiner would note that recitation of column agglutination technology for visual analysis is in the alternative.

Claims 16, 20, 22, 23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chachowski et al (U.S. Pat. No. 5,552,064) in view of Shen et al (U.S. Pat. No. 5,594,808) for reasons of record in the prior rejection of the similar subject matter of claims 16, 17, and 19-24.

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Applicant's arguments filed 06 August 2001 have been fully considered but they are not deemed to be persuasive.

Applicant urges that Ullman, alone or as modified, does not teach column agglutination or visual detection thereof. This is not found persuasive as the recitation of these limitations is in the alternative and, as such, is not required by the invention as claimed. The reference clearly meets the spectrophotometric alternative as there is nothing disclosed or in evidence to exclude detection of fluorescence from "spectrophotometric." Indeed, Vorpahl et al teach light emission by a fluorophor as a well known "spectroscopic" property (see e.g. col. 9). Notwithstanding applicant's argument to the contrary, for the reasons of record the reference of Ullman as modified teaches detection of simultaneously agglutinated cell populations.

In response to applicant's argument that the references of Yves [Lapierre] et al (U.S. Pat. No. 5,338,689), alone, or Chachowski et al (U.S. Pat. No. 5,552,064), alone or as modified, fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e.: erythrocytes stained with a dye; two distinct cell populations agglutinating in a single column) are not recited in the claim(s) rejected over these references. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

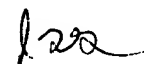
A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.


James L. Grun, Ph.D.
October 22, 2001


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641